## REMARKS/ARGUMENTS

Claims 1 and 3-29 were pending at the time of the mailing of the outstanding Office Action. Claims 16-25 have been withdrawn from consideration. In this amendment, claims 1, 3 and 5 have been amended. No claims have been cancelled or have been added.

In the Office Action of 9 June 2006, claims 3-5, 7, 8, 10, 12, and 14 were objected to as depending from a rejected claim. Claims 1, 5-13, and 26-29 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 6,254,632 to Wu et al. (hereinafter "Wu"). Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as unpatentable over Wu. Claims 14 and 15 were rejected under 35 U.S.C. § 103(a) as unpatentable over Wu in view of U.S. Pat. No. 6,287,628 to Hossainy et al. (hereinafter "Hossainy").

The undersigned attorney wishes to thank the Examiner for the courtesies extended during the telephone interview of 30 August 2006. During the interview, the nature and extent of the microcannulae of the present invention and those of Wu were discussed. The Examiner maintained that the previous amendment of claim 1 to recite that the microcannula(e) projects from the stent surface between about 100 and about 400 μm were not sufficient to specify which "surface" the length is measured from and therefore, the structures of Wu may be judged to anticipate the claims. That is, the Examiner maintained that the length of the structures of Wu could be measured from the "surface" of the bottom of the cavities of Wu and that this distance anticipated the microcannulae length of the present invention. Additionally, the Examiner maintained that the description of the cover of the stent of Wu could also support the interpretation of the structures of Wu having the same length as the microcannulae of the present invention. The Examiner maintained that the because Wu described the cover as having a thickness of 25 μm to 500 μm, and describes the structures as possibly protruding into or through the cover, the structures of Wu could have a length that encompasses all of the specified lengths of the microcannulae of the present invention. The Applicants'

attorney maintained however, that the common and ordinary meaning of the term "surface" precludes measurement of the height of Wu's structures from the bottom of the craters, which is necessary to arrive at a length of 100 to 400 μm as recited in claim 1. Given its ordinary meaning, the implant surface would be the portion of the implant closest to the vessel walls. Additionally, the specific disclosure of the "lip height" of Wu of 10-80 μm makes the Examiner's interpretation of the crater height relative to the cover thickness impossible, and the description of the cover thickness is consistent with the recited lip height of 10-80 μm. The Examiner also expressed concern regarding the use of "about" with regard to the recitation of the microcannulae length in the claims. Agreement was not reached regarding the claims.

The Applicants continue to maintain that the ordinary and usual meaning of the term "surface" provides more than adequate guidance regarding the proper measurement of the microcannulae length of the present invention. Webster's Ninth New Collegiate Dictionary (1984), defines a surface as "the exterior or upper boundary of an object or body." Clearly, this indicates that the surface of the implant is closest to the vessel wall. Additionally, claim 1 itself provides additional clarification of what is considered the "surface" by reciting that the microcannula penetrates into the media "when the implant bears in *surface* contact against a wall of the blood vessel..." (emphasis added). Clearly, the bottom of the microcannula well, can not bear in "surface contact" with the blood vessel wall. The surface, is therefore, the structure that bears against the blood vessel wall in use. Furthermore, if there can be any remaining potential ambiguity regarding the proper consideration of which structure constitutes the implant "surface," it is eliminated by the specification and drawings, which clearly indicate that structure 40 is the "surface" of the stent. See, for example, paragraph 0036, which states, "the microcannula projects by between 100 and 400 μm out of the surface 40 of the stent..." The "surface" of the implant is clearly and consistently referenced through out the specification and drawings as the exterior or upper boundary of the implant, consistent with the dictionary definition of "surface" as provided above.

Furthermore, the Examiner's interpretation of the surface of the stent as including the bottom surface of the craters of Wu is itself contradicted by the terminology used by Wu. Wu clearly differentiates between the "stent surface 114" and the "bottom surface 210" of the depression. (See, for example, column 5, lines 7-48.) That is, Wu also considers the surface of the stent to be "the exterior or upper boundary" of the surface of the implant. Wu clearly considers the "lip height" of his craters to be measured from the "stent surface" in the same way the Applicants measure microcannulae length from the implant surface. See, for example, Wu, column 5, lines 14-26.

The Applicants continue to maintain that Wu does not anticipate or make obvious claims 1 and 3-29. As the Applicants stated previously, Wu only indicates that the microstructures ("craters 200") engage the passageway of the lumen of a blood vessel when the stent is deployed. No teaching or suggestion is made that these structures are "raised out of the implant surface to such an extent that ... the microcannula penetrates into the media of the blood vessel" as recited in claim 1. Wu merely teaches that the "craters" "can be used to deliver therapeutic substances from the stent directly to the lumen wall..." (column 2, lines 60-62).

The Applicants further maintain that the Examiner has not given the term "media" its "plain meaning as interpreted by one of ordinary skill in the art." The specification clearly provides a precise definition of "media" sufficient for one of skill in the art to understand this term and the invention itself, against which the prior art should be compared. Paragraph 0034 provides a detailed explanation of the various layers of the blood vessel and precisely which layer is the media. This explanation is further supplemented by Fig. 1, which clearly illustrates the various layers and indicates the precise layer of cells considered to constitute the "media." Additionally, even assuming *arguendo*, that this usage of the term "media" is not an ordinary usage of those of ordinary skill in the art, the Applicants respectfully remind the Examiner that they are entitled to be their own lexicographers in the application and therefore their explanation

of the "media" layer should be adhered to when comparing the present invention to the teachings of the prior art.

Neither does Wu's description of a cover teach or suggest the present invention. The Examiner maintained during the interview that a cover with a thickness of 25 to 500 μm would be consistent with a "crater" lip height of 100-400 μm as recited. However, given the specifically recited lip height of Wu and wide range of thicknesses of the cover relative to the recited lip height, the Examiner's interpretation is not supported. For example, a lip height of 75 μm would be entirely consistent with structures of Wu that puncture a cover 25 μm thick. The same lip height would merely deform a cover that was 400 μm thick. At best, Wu's description of the cover thickness provides no additional clarification regarding the lip height. However, given the specific reference to lip height provided by Wu, the Examiner's inference of the lip height from the cover thickness must be considered incorrect.

As stated previously, the distinction between lip height and crater depth of Wu is significant because Wu provides a stent that includes structures that only allow delivery of a therapeutic substance directly to the wall of the vessel. Wu does not teach or suggest microcannulae that penetrate into the vessel wall. Wu merely provides that the protruding structures or craters "engage the lumen of the passageway ... to help prevent the stent from slipping out of the treatment site." Column 6, lines 15-17. Wu indicates that the craters 200 of their stent "engage the lumen of the passageway when the stent is deployed." Because the "lumen" of a blood vessel is actually the inner open space or cavity of the blood vessel, Wu can only mean that the craters 200 contact ("engage") the wall of the blood vessel at its surface.

Additionally, Wu's terminology (i.e. "craters") for these structures further indicates that Wu does not envision or intend for these structures to act as microcannulae penetrating into the media of the blood vessel as in the present invention. Rather, the structures are merely intended to engage and secure the stent to a vessel or to a cover for

the stent. Even assuming *arguendo*, that the craters of Wu had a sufficient height to act as microcannulae to deliver substances to the media of a blood vessel, Wu provides no indication that this height alone would be sufficient for these structures to act in this manner. It could be envisioned that a structure could have other dimensions such as the diameter of the structure or the lip width that would prevent it from penetrating into the media of a blood vessel. As stated previously, Wu provides no teaching or suggestion that these craters penetrate into the vessel past the endothelium, the basal lamina, and the inner elastic membrane and allow delivery of such substances directly into the media. In contrast, claim 1 recites that the microdevices of the present invention are "adapted for facing towards the blood vessel ... such that, when the implant bears in surface contact against a wall of the blood vessel, the microcannula penetrates into the media of the blood vessel." The structures of Wu are clearly not so adapted.

Therefore, the Applicants maintain that Wu does not teach or suggest all of the elements of claim 1, namely, a stent having a microcannula that extends from the surface between about 100 and about 400 μm and that penetrates into the media of a blood vessel when the stent bears against the wall of the blood vessel. During the interview, the Examiner expressed concerns regarding the potential for overlap between the upper end of the range of the lip height of Wu and the lower end of the microcannula length of the present invention, due to the use of the term "about". Although the undersigned attorney is unaware of any decisions of the Board of Patent Appeals and Interferences or any US court that would tend to indicate that the term "about" would allow a variance of 20 percent from an expressed value, in the interest of economy of prosecution, claim 1 has been amended to eliminate the use of the term "about" in connection with the lower end of the range of microcannula height. Therefore, claim 1 patentably distinguishes over Wu. Likewise, claims 5-13, and 26-29, which directly or indirectly depend from claim 1, and contain all the limitations of claim 1 also patentably distinguish over Wu. Withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

Claims 3 and 4 stand rejected as obvious over Wu. Claims 14 and 15 stand rejected as obvious over Wu in view of Hossainy. Neither Wu nor Hossainy, either independently or in combination, teach or suggest a stent having microcannulae that extend from the surface between about 100 and about 400 μm and that penetrate into the media of a blood vessel when the stent bears against the wall of the blood vessel, as detailed above. In fact, Hossainy only provides a "depot or pore 22" in the structure of the stent that may carry a therapeutic substance or other material. Hossainy provides no teaching or suggestion of a structure that extends from the surface of the implant at all, much less by 100-400 μm, or 150-300 μm, or 180-250 μm, as recited in claims 1, 3 and 4. Therefore, one of ordinary skill in the art would not have found any suggestion or motivation to modify the length of the craters of Wu to 100-400 μm, or to 150-300 μm, or to 180-250 μm, or to any other length.

Contrary to the Examiner's assertions, the Applicants have provided a distinct advantage of the claimed microcannula length ranges, namely, to deliver therapeutic products directly into the media of blood vessels, not just to the interior surface of the blood vessels. Neither Wu nor Hossainy provide any teaching or suggestion that such delivery is desirable or possible. Therefore, the Applicants maintain that claims 3, 4, 14, and 15 patentably distinguish over Wu, either alone or in combination with Hossainy. Withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

Because claims 1, 3-11, 14, 15 and 26-29 are generic for all species within elected Invention I, rejoinder of non-elected claims 16-25 is hereby requested.

Amendments to claims 3 and 5 have been amended to correct the dependency of these claims. Withdrawal of the objection to claims 3-5, 7, 8, 10, 12, and 14 as depending from a rejected claim is also requested.

The outstanding Office action was mailed on 9 June 2006 and a response is timely if filed on or before 11 September 2006, as 9 September 2006 falls on a Saturday. No

fees are believed to be due with the filing of this response. However, in the event that a fee for the filing of this response is insufficient, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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